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09/529,128	06/30/2000	GRAHAM FRANCOIS DUIRS	42341-350041	2910

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/529,128	Applicant(s) DUIRS, GRAHAM FRANCOIS	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,9,11,14 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,9,11,14 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 8/28/2009.
2. In the reply, the applicant amended claims 1, 3-5, 8-9, 11, 14, 21, and added new claims 22-32.
3. Thus, claims 1, 3-5, 8-9, 11, 14, 21-32 are pending for examination.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/28/2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 29 and 30 recites having two resilient arms "facing one another". The Examiner is unsure what the limitation is intending to mean. The applicant has not defined a side/face of the resilient arm and thus has no idea how they can face one another as claim. Appropriate structural clarification is required.
4. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 and 32 recite that the two resilient arms

are offset with respect to one another. The examiner is unsure what the claim limitation should mean. What does offset mean? How are the resilient arms offset with respect to one another? The examiner believes the applicant needs to additionally recite a characteristic of the offset to get any meaning to the claim. For example, the two resilient arms are offset in length with respect to one another would require one arm to be shorter/longer than the other arm.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1, 3-5, 8-9, 11, 14, 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soichet (3678924) in view of Hiller et al (4369783). Soichet discloses an internal substance delivery device for insertion into a vaginal cavity having a support frame (34) and at least two resilient arms (20, or 29, or P; Figs 1-4) tensioned outwards from a central section of the support frame towards a muscosal membrane of the vaginal cavity when the device is in situ, the outward tensioning retaining the device in the vaginal cavity against the muscosal membrane (Figs 1-4; Description); each capable of being compressed (Figs 1-4); a drug delivery portion attached at or near a distal end (24, 26, N; Figs 1-4); a wishbone shape (Figs 1-4); the support frame being made of nylon (col 2, lns 66-74; col 4, lns 11-19); a locator (Q, S, T; Fig 4); substantially S-shaped arms that face one another and are offset (Figs 1-4).

7. However, Soichet does not disclose a separate pod capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame. Hiller et al teaches that it is known to have a separate pot capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame (Figs 1-17; 4a; col 4, lns 37-col 5, lns 51; and col 5, lns 30-42 (osmosis); rounded (col 4, lns 22-25); and ball and socket (col 3, lns 8-11); and additionally see discussion of 102(b) rejection in Non-Final Rejection mailed 1/7/2009) for the purpose of contacting a mucosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery ends as taught by Soichet with the ball and socket pods as taught by Hiller et al for the purpose of contacting a mucosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa.

8. Claims 1, 3-5, 8-9, 11, 14, 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al (4038978) in view of Hiller et al (4369783). Morris et al disclose an internal substance delivery device for insertion into a vaginal cavity having a support frame (12) and at least two resilient arms (14, 16) tensioned outwards from a central section of the support frame towards a mucosal membrane of the vaginal cavity when the device is in situ (Figs 1-5; Summary), the outward tensioning retaining the

device in the vaginal cavity against the muscosal membrane (Summary); each capable of being compressed (Summary; Fig 5); a drug delivery portion attached at or near a distal end (18, 20); a wishbone shape (Figs 1-5); the support frame being made of nylon (col 4, lns 14-26); a locator (38, 41); substantially S-shaped arms that face one another and are offset (Figs 1-5; wherein offset is in length – see Fig 5).

9. However, Morris et al does not disclose a separate pod capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame. Hiller et al teaches that it is known to have a separate pot capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame (Figs 1-17; 4a; col 4, lns 37-col 5, lns 51; and col 5, lns 30-42 (osmosis); rounded (col 4, lns 22-25); and ball and socket (col 3, lns 8-11); and additionally see discussion of 102(b) rejection in Non-Final Rejection mailed 1/7/2009) for the purpose of contacting a muscosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery ends as taught by Morris et al with the ball and socket pods as taught by Hiller et al for the purpose of contacting a muscosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa.

10. Claims 1, 3-5, 8-9, 14, 21-25, 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (5816248) in view of Hiller et al (4369783). Anderson discloses an internal substance delivery device for insertion into a vaginal cavity having a support frame (38) and at least two resilient arms (48, 58) tensioned outwards from a central section of the support frame towards a muscosal membrane of the vaginal cavity when the device is in situ, the outward tensioning retaining the device in the vaginal cavity against the muscosal membrane (Figs 1-3; Abstract; col 3, lns 52-67; col 4, lns 18-col 5, lns 37); each capable of being compressed (Figs 1-3; Abstract; col 3, lns 52-67; col 4, lns 18-col 5, lns 37); a drug delivery portion attached at or near a distal end (54, 64; Fig 3); a wishbone shape (Figs 3); a locator (68); the arms face one another and are offset (48, 58; Fig 3).

11. However, Anderson does not disclose a separate pod capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame. Hiller et al teaches that it is known to have a separate pod capable of releasing a drug contained within a matrix via osmosis, wherein the pods are flexibly attached to a corresponding arm by a ball and socket mechanism allowing 3-D movement with respect to the support frame (Figs 1-17; 4a; col 4, lns 37-col 5, lns 51; and col 5, lns 30-42 (osmosis); rounded (col 4, lns 22-25); and ball and socket (col 3, lns 8-11); and additionally see discussion of 102(b) rejection in Non-Final Rejection mailed 1/7/2009) for the purpose of contacting a muscosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify the drug delivery ends as taught by Anderson with the ball and socket pods as taught by Hiller et al for the purpose of contacting a muscosal membrane with a drug body in a free-moving manner to decrease the mechanical strain on the mucosa.

Response to Arguments

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

13. The Examiner further notes that having two tensioning resilient arms as claimed by the applicant are known in the art. See PTO-892 form.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 Form.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

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Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767